

**SUN SHADES LIP BALM TROPICAL FRUIT SORBET- avobenzone 2.5%, octinoxate 6%, oxybenzone 3% stick
Melaleuca Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sun Shades Lip Balm - Sunscreen

Tropical Fruit Sorbet - Broad-spectrum SPF 15

Active ingredients

Avobenzone 2.5%, Octinoxate 6%, Oxybenzone 3%

Purpose

Sunscreen

Uses

■ helps prevent sunburn ■ if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ apply liberally 15 minutes before sun exposure

■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating ■ children under 6 months of age: ask a doctor

■ **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures including: ■ limit time in the sun, especially from 10 a.m.-2 p.m. ■ wear long-sleeve shirts, pants, hats, and sunglasses

Other information

■ dermatologist and allergy tested

■ protect this product from excessive heat and direct sun ■ do not store at temperatures below 32 F (0C) or above 120F (48C)

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age: ask a doctor
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and

petrolatum usp, ceresin, ~~ammonium~~ chinensis (jojoba) seed oil, euphorbia cerifera (candelilla) wax, cetyl esters, theobroma cacao (cocoa) seed butter, C12-15 alkyl benzoate, flavor, stearyl dimethicone, tocopheryl acetate (vitamin E USP), ethylene/VA copolymer, ammonium glycyrrhizate

SUN SHADES LIP BALM STROPICAL FRUIT SORBET

avobenzone 2.5%, octinoxate 6%, oxybenzone 3% stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-255
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.1175 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.282 g in 4.25 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.141 g in 4.25 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ETHYLENE-VINYL ACETATE COPOLYMER (40 % VINYL ACETATE) (UNII: L5F16ZG4ZU)	
JOJOBA OIL (UNII: 724GKU717M)	
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-255-01	4.25 g in 1 APPLICATOR; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2012	

Labeler - Melaleuca Inc. (139760102)

Registrant - Melaleuca Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca Inc.		079711683	manufacture(54473-255)

Revised: 5/2016

Melaleuca Inc.